Update PCB Exposure Estimation Tool - Internal Comments and Responses

Reviewer Recommendation	Number Comment	Response	Addressed	Addressed in Document	Notes
rchfield (OLEM) Acceptable as is (provided some suggestions)	reviewers and users might benefit from a consolidation of uncertainties and assumptions. Good things to note from my perspective is the variability in background (particularly diet), assumptions regarding cumulative effects from different PCBs and different routes of exposure. If this is done, it would be good to	The Tool provides information on the input assumptions on Tab D. Although central tendency values have been used as 'defaults' additional information is provided on upper percentile values, and the user can change the 'default values as needed to represent site-specific conditions. The FDA memo explaining the dietary data have been added to a new tab (see comment number 3 below) and a caveat regarding the dietary data was added previously. EPA has used the Tool (with the default values) to calculate ELEs. These ELEs are described on EPA's website entitled "Exposure Levels for Evaluating Polychlorinated Biphenyls (PCBs) in Indoor School Air" (https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-school-air). Questions and answers regarding the ELEs are provided in https://www.epa.gov/sites/production/files/2016-03/documents/pcbs_in_building_materials_questions_and_answers.pdf. These files provide the basis for the ELEs and some information on uncertainties. Perhaps these would be better places to further discuss uncertainties associated with the ELEs (the Tool is the means for developing the ELEs). However, a footnote has been added on Total Exposures Tab E of the Tool to refer users to these websites.	Yes	NA	Spoke with Norm on May 2 2019 to discuss his commer and how they are being addressed.
	ELEs are described as "health protective", which implies that exposures above the median would be covered. Given the range of concentrations measured in the background media, is this accurate? Because the highest PCB concentrations in some of the media measured are many fold greater than the mean/median values used to calculate background it would be good to include a characterization of how this could affect the results.	This comment pertains to a statement in the document on the systematic review to update the Tool but not on the Tool itself. This language is quoted from EPA's website on the ELEs (https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-schoolair). Thus, no change to the systematic review document is needed. The ELEs are considered to be "health protective" because they keep the total dose at or below the RfD considering average background exposures from other sources. Note that the quote also says that they are intended to be used "to guide thoughtful evaluation of indoor air quality in schools" and should not be applied as "bright line" or "not-to-exceed' criteria.	, NA	No	
	Given the relative importance of the dietary contribution it would be good to include a more detailed reference and supporting information if possible.	The dietary data used in the Tool are based on FDA's Total Diet Study which are summarized in a personal communication (letter) between Judith Spungen (FDA) and Linda Phillips at (EPA). An image of the letter from FDA with the dietary data has been added on a new Tab L of the spreadsheet and referenced in the introduction Tab A, background Tab B, and how-to Tab C of the Tool.	Yes	NA	
		There are 2 sections of calculations on Tab E. The upper portion on provides estimates of total doses of PCBs from school and non-school sources. Since inhalation is one of the indoor school sources it needs to be included so that the it is included in the total dose. The bottom portion of Tab I estimates the Indoor school air concentration that you could have without exceeding the RfD. It uses the total dose minus the indoor school inhalation and calculates what is left of the RfD that can be taken up by inhalation of indoor school air and converts it to a concentration in air. You will find that if you enter the estimated maximum concentration in indoor school air as the concentration in indoor school air, the total estimated dose will equal the RfD. Additional spacing has been addd to separate these 2 portions of the spreadsheet. Also, a footnote has been added to Tab E to explain the calculation of the maximum concentration in indoor school air without exceeding RfDAs follows: "Calculated as the RfD minus the total dose plus the indoor school inhalation; remainder is converted to the concentration in indoor school air to which individuals can be exposed without exceeding the RfD: Conc _{alcmax} = [(RfD - Total Dose + School Inhalation Dose) x Body Weight] / [Inhalation Rate x Fraction of Time in School x Relative Absorption]."		NA	
	For the IRIS RfD reference in the references tab, I suggest putting a bit more detail on where to find the specific RfD used. Providing a link to the Tox Review or IRIS Summary would be helpful.	The link to the IRIS summary has been added to the reference Tab K and cited in the background Tab B of the Tool.	Yes	Yes	
	I know the document provided isn't part of the review but I'll just note that I like the systematic review but feel that for those who are new to it that the PECO terms are distracting, jargony, and would be better replaced with analogous descriptive terms that better fit this application.	These are standard terms being used by the systematic review community. Since we are trying to follow these standard procedures, the use of these terms seems appropriate here. No change to the document is required.	NA	No	
ria Doa (OSP) Acceptable after minor revision	The PCB Exposure Estimation Tool is clear and well documented. 7	No response needed.	NA	NA	Spoke with Maria on June 2019 to discuss her comme and how they are being addressed.
	Tab B, 1st paragraph - "It is assumed that PCBs from school buildings would not affect food" Is this because the contribution from settling on food, including in cafeterias is assumed to be de minimis? If it is de minimis, I recommend stating that. 6th paragraph – same point.	The Tool uses total dietary PCB estimates for the general population. It is assumed that dietary exposure to PCBs would be the same for students as the general population. The wording in Tab B has been revised to clarify this as follows: "The contaminated school scenario includes estimates for the same exposure routes except that no estimate for dietary ingestion is included, because the FDA dietary estimates used in the non-school scenario represent total dietary exposure. Also, these total dietary estimates represent the general population, and it is assumed that total dietary exposures for students would not differ from those of the general population."	_	NA	
	Tab B, Penultimate paragraph. I recommend adding another sentence clarifying a bit more why you are using Arochlor 1254. Is the point, that even though the PCB mix remaining is different than the original mix, Arochlor 1254 is still the most representative congener? If so, I believe that is worth stating.	Text has been added to indicate that the RfD for Aroclor 1254 was used because it is the more conservative of the available RfDs for PCB Aroclors as follows: "This RfD is the more conservative RfD of those available for PCB Aroclors in EPA's IRIS database (U.S. EPA, 2019)." A similar statement was made in Tab A Introduction.		NA	
	Tab D, Dermal surface area (Variable name SA). Is the number for	Could not find where a word was missing in the 1st paragraph 3rd sentence, but did find a word missing in the 2nd paragraph, 4th sentence and fixed it by adding "in." These values are correct, as reported in the Exposure Factors Handbook: 2011 Edition. They are average values for these age groups. While the	Yes	NA	
	hands for 2 to <3 yrs correct? The number is smaller than the corresponding number for 1 to <2 yrs. Tabs D and K – Dietary dose assumptions.	value for hands in slightly lower for 2 to <3 years than 1 to <2 years, the total surface area in larger and that is what is used in the calculations. No changes to the Tool or document are needed. The dietary intake values can be modified, if needed (only grayed-out cells cannot be modified). The following sentence was added to Tab K:	No	NA	
	Why is this not an assumption that can be modified to take into account those communities that consume fish at a high concentration than the general population? I would think that for some communities this would be an important factor. Further, this could be construed to be a policy factor given that there are vulnerable populations that are known to consume larger	"Users can modify these dietary values if desired."	Yes	NA	
f Frithsen (ORD)	quantities of fish than the general population and thus may have higher PCB dietary intakes. 13 No comments received				
er Gimlin (OPPT) Acceptable as is Haklar (R2)	14 No comments except "very thorough and well written." 15 No comments received		NA 	NA 	
niece Lehmann (NCEA) Acceptable as is	Insert the word 'information' after 'background' in the 2nd paragraph of the introduction in the systematic review document. Delete 'the' in the last sentence of Section 3.1.1.1 of the systematic	Edited as suggested. Edited as suggested.	NA NA	Yes	Spoke with Geniece on Jur 4, 2019 to discuss a comme from Kim Tisa on the RfD for PCBs.
Acceptable as is (provided some suggestions)	Tab B, Cell B17: Perhaps could add here that EPA consulted with	The following statement was added as suggested: "On February 5, 2019, Linda Phillips, EPA, contacted Judith Spungen, FDA, to inquire about whether more recent TDS exposure estimates for PCBs were available, and was informed that the 2003 TDS are still the most recent data set for PCBs."	Yes	NA	Spoke with Mario on June 2019 to discuss his second comment.

	Tab B, Cell B21: Would this reference to PCB concentrations in environmental media generally derived for Aroclor 1254 still be valid if we considered that painted walls and tiles in some buildings could be a significant source for PCB emissions to indoor air and dust? Is the reference to Aroclor 1254 important here since the calculated ELEs (Tab E) will be compared to the total measured PCB/Aroclor concentration in a sample of indoor air?		Yes	NA	
	Tab D, Exposure Factors: For reporting population mean data derived for tables in the Exposure Factors Handbook, does the Handbook generally consider that the population is weighted equally between males and females (50:50) regardless of the actual population distributions by sex in the original data collection studies? Therefore the estimation Tool uses the combined male/female mean data for the Exposure Factor variables. This is a valid approach for the Estimation Tool because the PCB daily doses are compared to the PCB Reference Dose for potential daily exposure which applies to all individuals across the U.S population		No	NA	
	21 Tab D, Cell B21: Should this Cell contain a variable name? Tab E, Background Exposures and School Exposures: Are there	Yes, ADD _{food} has been added here. The values have all been set to show 1 decimal place. Thus, small values (i.e., those below 0.1) appear as 0. No change to the Tool is needed.	Yes	NA	
	specific criteria applied to determine that the Daily Dose for an intake pathway should be listed as "0 ng/kg-day"? It looks like most calculated daily doses below 0.1% of the Total were listed as "0" but in one case, a calculated daily dose of 0.5% was listed as "0 ng/kg-day" (Cell I17).		No	NA	
Marian Olsen (R2) Acceptable after minor revision	Tab A. The introduction does not appear to explain how the exposure information may be used to support a decision at a School. It is suggested that the following language from the Peer Review document be included in the introduction.	The following sentence was added to the first paragragh in Tab A: "The Tool may be also used to calculate the maximum PCB concentration in indoor school to which individuals could be exposed without exceeding the reference dose (RfD) (see Tab E) when all other school and non-school PCB exposure pathways are set to average background levels." The definition of an RfD and the information about Aroclor 1254 being the more conservative of the Aroclor has already been added to this Tab (row 11) based on comments received from another commenter.			
	The Tool (Appendix E) may be used to calculate the maximum PCB concentration in indoor school to which individuals could be exposed without exceeding the reference dose (RfD) a measure of toxicity for PCB Aroclor 1254 (the more conservative of the two RfDs available for PCB Aroclors) when all other school and nonschool PCB exposure pathways are set to average background levels. The Exposure Levels for Evaluating PCBs in Indoor Air (ELEs) were derived to serve as health protective values intended for evaluation purposes. They should not be interpreted nor applied as "bright line" or "not-to-exceed" criteria, but may be used to guide thoughtful evaluation of indoor air quality in schools."		Yes	NA	
	Tab A. It is also suggested that the text in this paragraph define the term Aroclor. Suggested language is provided below: Throughout the Tool, Aroclor 1254 is mentioned. It may be helpful	The following text has been added as a footnote on Tab A: "Aroclors are a PCB mixture manufactured and used from approximately 1930 to 1979. Aroclor 1254 evaluated in this Estimator Tool means that the mixture contains approximately 54% chlorine by weight." Information about this being the more conservative of the RfDs, and the definition of an RfD has already been added based on comments from another reviewer.			
	to define Aroclor either in the text of a footnote. Suggest language is: Aroclors are a PCB mixture manufactured and used from approximately 1930 to 1979. Aroclor 1254 evaluated in this Estimator Tool means that the mixture contains approximately 54% chlorine by weight. PCB Aroclor 1254 is also the most conservative of the two toxicity values or Reference Doses used to evaluate hazards from exposure that are available for PCB Aroclors. Tab B. Here, and through the Tabs, there are a number of terms	6	Yes	NA	
	that are not defined. For example, ug/kg-day, ng/kg-day and in Appendix D for other units. It may be helpful to have a list of acronyms included as a Tab for reference. Suggest defining FDA in the first paragraph where it first appears.	defined on Tab I. FDA has been defined in the first paragraph and abbreviated in the sixth paragraph as suggested.	Yes	NA	
	Currently, it is mentioned in the first paragraph and defined in the sixth paragraph. Tab D. Suggest defining terms such as central tendency, units of measure such as ug/g, ng/m3, mg/cm2, etc. this information may be included in Glossary that is available as a Tab in the document.		No	NA	
	Tab E. It may be helpful to include a discussion regarding comparing the results to the oral Reference Dose provided on Line	An explanation of how to interpret the ELEs that are derived from use of this Tool are provided on EPA's website (https://www.epa.gov/pcbs/exposure-levels-evaluating-polychlorinated-biphenyls-pcbs-indoor-school-air). The website indicates regional PCB coordinators should be contacted if needed. Since the Tool is simply a means for calculating exposures and maximmum concentraions, it may be better to leave the discussion of how to interpret and use the values to the website. No change to the Tool has been made.	No	NA	
	Tabs F and G. Suggest here, and throughout the text, that the term "site" not be included to avoid potential confusion with Superfund site. If the term is used, it will need to be defined earlier in the document. Perhaps the work location may work better here? It would also be helpful to explain how to interpret the terms		Yes	NA	
	background and percent of total dose. An example may help so the reader understand the significance of the results. Tab H. Suggest providing links to the various documents listed here. Suggest including a link to the ATSDR Tox Profile and also the Tox				
	Fax document. One reference is: https://www.atsdr.cdc.gov/ToxProfiles/tp.asp?id=142&tid=26. It is not clear why USEPA 2003 is listed and further information	A link to the IRIS file for Arodor 1254 has been added.			
	needs to be provided regarding how this relates to the PCB assessment. It does not appear that dioxin-like congeners are being evaluated here so it is not clear why this document is provided as a reference. For the IRIS chemical files, suggest providing a specific link to the Aroclor 1254 or indicate that the user should search for Aroclor 1256 on the IRIS database.	4	Yes	NA	
Kent Thomas (NERL) Acceptable after minor revision	Overall the Tool has been constructed with great quality and care. The approach for combining backgrouns and school exposure for multiple environmental media and diet is well conceived and executed. The exposure estimation calculations have been correctly formulated and applied. THe Tool is highly transparent and allows users to adjust input values to make different population and/or site-specific assessments. The documentation accompanying the information and applications in the Tool is outstanding and adds to the excellent transparency.	No response needed.	NA	NA	

	In general, the recent systematic literature review and data extraction were performed adequately and resulted in additional information to support the background input data used in the Tool. Please see comments in the document for one potential journal article that may have been missed and may add to information on U.S. residential dust PCB levels. This reviewer performed calculation checks for the V2 ELE values and obtained 100% agreement with those values. The calculation check spreadsheet is provided as part of this review.	The journal article has been reviewed and added to Appendix C. However, it was not included in the average value for dust because while it is not entirely clear in the paper, it appears that the author may have provided total PCB values for the 20 samples that are based only on the congeners that were also found in the serum of the residents representing only 21 peaks of the 62 peaks detected.	Yes	NA	
	The document that has been prepraed to describe the Tool and provide the V2 ELE values does a good job of balancing conciseness and necessary information. A tracked-change version of the document is being provided with some comments and recommendations for author consideration. Some clarification of how the new reference input data was or was not combined combined with the Vi input value data would be helpful. However no major changes are needed in the document.		NA	Yes	
	Please also see some comments and minor suggested edits in Appendices A - H.	Edits to the appendices have been made based on the suggested edits in the tracked-change version provided by the reviewer.	Yes	Yes	
Kim Tisa (R1) Acceptable after minor revision	The document indicates that the Tool could be used to assess exposure at non-school sites. However the document lacks discussion on how the derived numbers consider sensitive populations such as pregnant women, nursing women, and children less than 1 ppm. While these populations may not be considered, I would suggest some inclusion of a statement on this matter.	Based on a conversation with Kim, it appeared that her primary question was whether the RfD was protective of sensitive populations. In response to her concern, the following was added to Tab A Introduction of the Tool. The IRIS glossary (https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/glossariesandkeywordlists/search.do?details=&glossaryName=IRIS Glossary) defines an RfD as "an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure for a chronic duration (up to a lifetime) to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." A similar statement was already in Tab B Background.	Yes	NA	Spoke with Kim on June 3, 2019 to discuss her comments and how they are being addressed. Also, consulted with Geniece Lehmann about Kim's question on the RfD.
	The Tool Background Section (Tab B) for Dermal Exposure states that "Dermal absorption from direct contact with caulk or other PCE impregnated surfaces is assumed to be negligible and is not included." It is not clear what is mean by "other impregnated surfaces". Further, what evidence is available that supports derma contact is negligible risk? We have certainly seen PCB concentrations in surface wipe samples collected directly from caulk. With material such as paint, the concentrations in surface wipe samples are generally lower. If the PCB impregnated surface is contaminated from a liquid vs a non-liquid, certainly the dermal exposure could be greater. Thus, it would seem that this concept warrants further consideration.	The caveat on Tab B for Dermal Exposure has been revised as follows: "Dermal absorption from direct contact with caulk or other PCB impregnated surfaces (i.e., non-liquid materials such as surfaces with PCB-containing paint) is assumed to be low because of the limited access to these materials (i.e., low contact) and is not included."	Yes	NA	
		The ELEs themselves are not discussed in the Tool because the Tool is simply the means for estimating the maxium air concentration to which individuals can be exposed without exceeding the RfD. The maximum concentrations estimated by the Tool are then used by EPA to develop the ELEs which are the maximum concentrations rounded to the nearest hundred. A footnote has been added to the document to indicate the reason for rounding these values ("Because of the various uncertainties associated with the input values in the Tool (e.g., background media concentrations, exposure factors, RfD) maximum indoor air concentrations without exceeding the RfD were rounded to one significant figure to represent the ELEs"). A footnote on Table 6 indicates that these values have been rounded from the values calculated by the Tool, as shown in Table 5 (Page 12). Perhaps the additional footnote should be added to the website and Q&As when the new ELEs are posted.	NA	Yes	
Mike Slimak (ORD) Acceptable as is	37 No comments provided except "Nice work!"		NA	NA	
Patrick Wilson (R9) Acceptable as is	In general, we find that the tool and supporting documentation is adequate and efficiently achieves the stated objectives pursuant to its development. Further, we believe the documents Content & Scope; Organization & Presentation; Data Quality & Validity; Soundness of Conclusions; and Editorial Quality are superior and	No response needed.	NA	NA	
	satisfactorily fulfill the goals of the intended purpose.				-
	Section 2.0 Background & Purpose. School & Non-school PCB sources of exposure have been set to average background concentrations in support of the derivation of PCB ELEs. The application of mean (average) PCB background concentrations rather than the use of more high-end background estimates should be explored in future versions of this tool. Regional Office site-specific risk assessments typically use parameters which characterize more high-end human exposure estimates (Upper confidence Limits on the mean [UCLs] or Reasonable Maximum Exposure [RME]) estimates when characterizing the human exposure potential at contaminated sites or structures. The impact of mean vs more high-end background exposure estimates should be explored with respect to their	The Tool uses central tendency values for backgound concentrations and is intended to represent 'typical' exposures among the general population. Users can modify these values, as needed, to calculate exposures for specific locations or populations, or to estimated high-end exposures. Tab D (Inputs & Assumptions) provides ranges of values from the various studies used in the Tool which could be used to estimate high-end exposures. No changes to the Tool have been made.	No	NA	
	Section 2.0 Background & Purpose. School & Non-school PCB sources of exposure have been set to average background concentrations in support of the derivation of PCB ELEs. The application of mean (average) PCB background concentrations rather than the use of more high-end background estimates should be explored in future versions of this tool. Regional Office site-specific risk assessments typically use parameters which characterize more high-end human exposure estimates (Upper confidence Limits on the mean [UCLs] or Reasonable Maximum Exposure [RME]) estimates when characterizing the human exposure potential at contaminated sites or structures. The impact of mean vs more high-end background	population. Users can modify these values, as needed, to calculate exposures for specific locations or populations, or to estimated high-end exposures. Tab D (Inputs & Assumptions) provides ranges of values from the various studies used in the Tool which could be used to estimate high-end exposures. No changes to the Tool have been made. The commenter is correct that the RfD for Aroclor 1254 is roughly equivalent to a 1E-5 cancer risk. Thus, ELEs based on a E-6 risk would be roughly 10 times lower. Deriving the ELEs based on cancer risks would require major revisions to the Tool. No changes to the Tool have been made at this time.	No	NA	

Info air 8 curr cond provided in the condition of the con	The commenter is correct that changes in the concentrations of some media result in little if any changes to the results because of their small contribution has been provided on the dust, soils, indoor & outdoor & dietary exposure concentrations that were selected for the rent version of the estimation tool. These media concentrations share been contrasted with the concentrations when in pared with past values. The dominant pathway for human PCB possure (Dietary Ingestion) did not include significant changes to exposure estimates. It may be useful to include a test of tistical significance in future updates of PCB media concentrations of some media result in little if any changes to the results because of their small contribution to overall exposures. For this version of the Tool, the updated media concentrations are very similar to those in the original version of the Tool. Thus, the ELEs did not change significantly. The author's suggestion to evaluate which media concentrations significantly affect the ELEs before embarking on a future update is a good one. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed. No changes to this version of the Tool are needed.	No	NA
The crite typi 43 Con chro	The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another reviewer, a footnote has been added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on a suggestion by another left added to Tab E to show how the maximum indoor air concentration without exceeding the RfD was calculated. The oral RfD for Aroclor 1254 was used directly with no conversion to an RfC. Based on	Yes	NA